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10/813,098	03/31/2004	Odile Aubrun-Sonneville	238275US0	5536

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EXAMINER

KAROL, JODY LYNN

ART UNIT	PAPER NUMBER
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1609

NOTIFICATION DATE	DELIVERY MODE
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10/05/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/813,098

Applicant(s)

AUBRUN-SONNEVILLE ET AL.

Examiner

Jody L. Karol

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/31/2004 and 8/16/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending in this application, and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 3/31/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.
2. The information disclosure statement filed 8/16/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because, it is not a proper IDS, but merely a list of related cases. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

3. The abstract of the disclosure is objected to because it refers to "one particular amphiphilic" polymer, but the general composition of the polymer is not given. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. The use of the several trademarks has been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13-14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "substantially free of emulsifying surfactant" in claim 11 renders the claim indefinite. The amount of surfactant that could be present in the composition for it to still be considered "substantially free of emulsifying surfactant" is indeterminable.

The recitation of "and/or" in claims 13-14 renders the claims indefinite because it is simultaneously inclusive and exclusive.

Claim 17 is indefinite because the weight-average molecular weight does not have a unit of measure.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 22-27, and 29-49 of U.S. Patent No. 6,905,674 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim compositions suitable for topical application that comprise an oily phase dispersed in an aqueous phase and a non-cross-linked amphiphilic copolymer comprising of (a) acrylamido-2-methylpropanesulfonic acid (AMPS) units and (b) units of formula (II) in the instant claims (which is analogous to formula (3) of the patented claim 24). The claims also claim methods of protecting the skin, lips, or hair by applying the composition.

The only significant difference between the instant claims and the patented claims is that the instant claims additionally require the presence of a wax. However, claim 46 of the patented claims indicates that the composition further comprises a cosmetic adjuvant selected from ingredients commonly employed in the cosmetic or dermatological field. One of ordinary skill in the art

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at the time of the invention would know that a wax is a commonly employed ingredient. Furthermore, claim 47 of the patented claims indicates that the composition can be a wax/aqueous phase dispersion.

Other differences between the instant claims and the patented claims are that the patented claims do not include specific weight percentages for the oily phase and the wax component and they do not claim specific properties for the wax, or the composition such as stability or viscosity. However, it would be within the purview of the skilled artisan to optimize the weight percentage of the components. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955). Furthermore, properties such as viscosity are inherent; a chemical composition and its properties are inseparable. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties the applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The patented claims also do not claim that the composition is surfactant-free as claimed in the instant claim 11, but only claim 46 claims that a surfactant may be present as a cosmetic adjuvant. Therefore, compositions without surfactant are considered within the scope of the patented claims.

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8. Claims 1-10 and 12-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/813,013.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim the identical composition, and overlapping methods of use for the composition, except that the instant claims require a wax component and the co-pending claims require a lipophilic emulsifier. However, it would have been obvious to one of skill in the art at the time of the invention was made to add a suitable wax component to the co-pending claims because waxes are a well-known cosmetic adjuvant, with well-known properties.

Other differences between the instant claims and the co-pending claims are that the patented claims do not include specific weight percentages for the oily phase and the wax component. Again, it is within the purview of the skilled artisan to determine an optimum working range for the components.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Morschäuser et al. (EP 1069142 A). US 6,645,476 B1 is used as the English equivalent.

The instant claims 1-17 are directed towards topical compositions and methods of use, where the composition comprises an oily phase dispersed in an aqueous phase, at least one wax, and at least one non-crosslinked amphiphilic polymer. The polymer comprises from (a) 80 to 99 mol% of 2-acrylamido-2-methylpropane-sulphonic acid (AMPS) unit of formula (I), and (b) 1 to 20 mol% of units of formula (II) in which n and p, independently of each other, denote 0 to 24, with $n+p < 25$; R_1 is a hydrogen or linear or branched alkyl radical containing from 1 to 6 carbon atoms, and R_2 denotes a linear or branched alkyl radical containing from 6 to 30 carbon atoms.

Morschäuser et al. teaches cosmetic compositions containing water-soluble polymers (see abstract). In a preferred embodiment, the polymer is a copolymer of the following macromonomers:

A) esters of (meth)acrylic acid with alkyl ethoxylates with 5 to 80 ethoxylation (EO) units; and

B) AMPS, or sodium and ammonium salts thereof,

wherein "A)" is preferably present in 10 to 20 mol % as claimed in the instant claims 1-17 (see column 3, lines 23-33 and column 4 lines 6-8). Morschäuser et al. further teaches that the suitable macromonomers "A)" are esters of

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(meth)acrylic acid with (C₁₀-C₂₂)-fatty alcohol polyglycol ethers with varying amounts of EO units and C₁₁-oxo alcohol polyglycol ethers with 8 EO units as claimed in the instant claims 4-5 (see column 3, lines 36-59). In addition, the polymers are neutralized with NH₃ as claimed in the instant claim 2 (see column 11, lines 19-20). Morschäuser et al. also teaches that the polymer is present in emulsions ranging from 0.05 to 10% by weight, which overlaps with the instant claim 6 (see column 5, lines 52-56). Morschäuser et al. teaches that the compositions can be water-in-oil emulsions or oil-in-water emulsions, and that the emulsions may also contain waxes as claimed in the instant claims 1-17 (see column 9, lines 14-15 and 27-32). The oily phase present in the emulsion ranges from 5 to 95% by weight, and preferably from 15 to 75% by weight as claimed in claim 7 (see column 9, 45-47). The composition may also be free of additional emulsifiers as claimed in the instant claim 11 (see column 5, lines 38-40). The emulsions are cosmetic preparations such lotions, creams, and ointments, and therefore suitable cosmetic or dermatological compositions as claimed in claim 12 (see column 5, lines 48-51)

Claims 15-16 of the instant claims are directed to the same composition as claim 1, but claim specific properties, such as stability and viscosity. As mentioned above, physical properties are inherent in the composition. "Products of identical chemical composition cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties the applicant discloses

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and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morschäuser et al. (EP 1069142 A) as applied to claims 1-7, 11-12 and 15-16. US 6,645,476 B1 is used as the English equivalent of EP 1069142 A.

Claims 1-7, 11-12 and 15-16 are described above. Claim 8 further requires the amount of wax to present in 0.1 to 10% by weight. Claims 9-10

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further require specific types of waxes. Claims 13-14 are directed towards methods of caring for, protecting, or making up the skin, sensitive skin, lips, or hair by applying the composition to the skin, sensitive skin, lips, or hair.

Morschäuser et al. teaches the oil-in-water compositions comprising the polymers as described above. Morschäuser et al. also teaches a specific example that additionally comprises a wax component, beeswax, in 2.00% by weight as claimed in the instant claims 8-9 (see column 20, Example 45).

However, the composition that Morschäuser et al. describes is a water-in-oil emulsion, and not an oil-in-water emulsion. The wax component is also not one of the specified waxes claimed in the instant claim 10.

Example 45 contains all the components as claimed in the instant claims 8-9. The additional components present in Example 45 do not distinguish the prior art from the instant claims because the term "comprising" in the instant claims is interpreted be broad and open. Water-in-oil emulsions and oil-in-water emulsions are well-known compositions for cosmetic and dermatological applications, and it well known in the art to adjust the components to get the desired emulsion type. The choice of wax in the example is also not viewed as limiting, as waxes are well known in the art, with well-known properties.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention that the oil-in-water emulsion containing a wax component as claimed in the instant claims 8-10, is an obvious variation of the water-in-oil emulsion taught by Morschäuser et al.

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Morschäuser et al. also does not specifically describe methods for using the methods. However, it is mentioned that the emulsions are preferably cosmetic compositions such as shampoos, shower gels, foam baths, lotions, creams, and ointments (see column 5, lines 48-51). It would be obvious to one of ordinary skill in the art at the time of the invention to use the compositions of Morschäuser et al. in the care of, protection of, make-up of the skin, sensitive skin, lips, or hair by applying the composition to the skin, sensitive skin, lips, or hair, because it is well-known in the art to use these types of compositions in this manner.

11. Claim 1-17 are rejected under 35 U.S.C. 103(a) as being obvious over Morschäuser et al. (EP 1069142 A) as applied to claims 1-16 above, in view of Lennon et al. (US 2003/0157047 A1), filed 10/15/2002. US 6,645,476 B1 is used as the English equivalent of EP 1069142 A.

The applied reference (US 2003/0157047 A1) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3)

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an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The instant claims 1-16 are described above. Claim 17 additionally specifies that the polymer has a weight-average molecular weight of 10,000 to 10,000,000.

Morschäuser et al. teaches the compositions containing the polymer as described above. Morschäuser et al. additionally teaches that the polymers generally have number-average molecular weight of from 1,000 to 200,000,00 g/mol.

However, the number-average is not the same as the weight-average molecular weight, and it is difficult to know how they compare without having knowledge of the polydispersity of the polymers.

Lennon et al. teaches the amphiphilic polymers of the instant invention in oil-in-water compositions (see abstract, page 4, sections 52-54, and page 5, section 76). Lennon et al. also teaches that the polymers have number average molecular weights ranging from 1,000 to 20,000,000 g/mol (see page 2, section 26). Therefore, it would be obvious to one of ordinary skill of the art at the time of

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the invention that the amphiphilic polymers of Lennon et al. could be used in oil-in-water emulsions as the amphiphilic polymers described by Morschäuser et al.

12. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being obvious over Lennon et al. (US 2003/0157047 A1), filed 10/15/2002.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Claims 1-17 are described above.

Lennon et al. teaches the amphiphilic polymers of the instant invention in oil-in-water emulsions (see abstract, page 4, sections 52-54, and page 5, section 76). Lennon et al. also teaches the specific (meth)acrylic acid esters as claimed in the instant claims 4-5 (see page 4, section 61) and that the polymer is neutralized as claimed in the instant claim 2 (see page 2, section 34). Lennon et al. teaches that polymer is present in a weight percentage overlapping with the instant claim 5 (see page 5, section 81), that the oil phase is present in a weight percentage overlapping with the instant claim 7 (see page 6, section 100), and that the polymer has a number-weight average overlapping with the instant claim 17 (see page 2, section 26). Lennon et al. further teaches that the polymer exhibits similar stability and viscosity profiles as claims in the instant claims 15-16, and that the composition can be free of an emulsifying surfactant as claimed in claim 11 (see page 10, section 154-158).

Lennon et al. does not teach a composition that contains a wax as claimed in the instant claims. However, Lennon et al. does indicate that a person skilled in the art is able to choose optional compounds to be added to the composition so that the advantageous properties intrinsically attached to the composition are not negatively affected (see page 8, section 130). Again, waxes are well known cosmetic additives with well-known properties. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention, to add the wax of the instant claims, particularly 8-10, to the composition taught by Lennon et al.

Lennon et al. further teaches the composition is useful for removing make-up or the cleaning of the skin or lips (see abstract). It would be obvious to one of

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ordinary skill of the art at the time of the invention that a method of caring for or making up the skin, sensitive, skin, or lips would be to apply the composition taught by Lennon et al. to the skin, sensitive, skin, or lips.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 02/43689 A (English equivalent US 2004/0109835) by Loffler et al. is important for its disclosure of cosmetic and dermatological compositions containing the amphiphilic polymer. The compositions may be oil-in water emulsions, surfactant-free, and optionally contain a wax. The percentages of the polymeric units are given in weight % instead of mol%. US 2003/0031643 A1 by L'Alloret et al. is important for disclosing water-in-oil emulsions comprising an amphiphilic polymer or copolymer of AMPS bearing hydrophobic grafts of (meth)acrylic acid esters.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 274-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK



**JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER**